GUIDE 61

General requirements for assessment and accreditation of certification/registration bodies

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Contents

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

Draft Guides adopted by the responsible Committee or Group are circulated to national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

ISO/IEC Guide 61 was prepared by the Committee on Conformity Assessment (CASCO).

Introduction

The requirements contained in this Guide are written, above all, to be considered as general requirements for bodies operating accreditation systems. This Guide, however, is in three sections so that if used by organizations other than accreditation bodies concerned with recognition of competence, Sections 1 and 3 apply, and users need simply replace "accreditation" by "recognition".

General requirements for assessment and accreditation of certification/registration bodies

Section 1: General

1.1 Scope

This Guide specifies general requirements for a body to follow if it is to be recognized at a national or international level as competent and reliable in assessing and subsequently accrediting certification bodies or registration bodies. Conformity to the requirements of this Guide will promote equivalence of national systems and facilitate agreements on mutual recognition of accreditations between such bodies.

The primary objective of this Guide is to describe accreditation as providing, by means of assessment and subsequent surveillance, an assurance that the market can rely on certificates issued by the accredited bodies. However, organizations other than accreditation bodies, concerned with recognition of competence, may also use it by replacing "accreditation" by "recognition".

In some countries, bodies which verify conformity of products, processes, services or systems to specified standards are called "certification bodies", in other countries "registration bodies", and in still others "assessment bodies". For ease of understanding, this Guide always refers to such bodies as "bodies". This should not be understood to be limiting, as this Guide may also be applicable to the assessment and accreditation of conformity assessment bodies other than certification or registration bodies, such as inspection bodies.

NOTE 1 It is recognized that agreements on mutual recognition of accreditations aiming at the removal of barriers to cross-border trade may have to cover other aspects not explicitly specified in these general requirements, such as the exchange of staff or training programmes. In particular, with a view to create confidence and harmonize the interpretation and implementation of standards, each accreditation body should encourage technical cooperation and exchange of experience among bodies accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies. Certification and certification/registration body standards often contain non-specific requirements such as "staff shall be competent". Mutual recognition of accreditation requires harmonization of interpretation of such clauses.

1.2 References

ISO/IEC Guide 2:1996, *General terms and their definitions concerning standardization and related activities.*

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories.*

ISO/IEC Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.*

ISO/IEC Guide 28:1982, *General rules for a model third-party certification system for products.*

ISO/IEC Guide 40:—[1], *General requirements for bodies operating product certification systems.*

1) To be published. (Revision of ISO/IEC Guide 40:1983)

ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/ registration of quality systems.*

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors.*

1.3 Definitions

For the purposes of this Guide, the relevant definitions given in ISO/IEC Guide 2 and ISO 8402 apply.

Section 2: Requirements for accreditation bodies

2.1 Accreditation body

2.1.1 General provisions

2.1.1.1 The policies and procedures under which the accreditation body operates shall be non-discriminatory, and they shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicant bodies other than as specified in this Guide.

2.1.1.2 The accreditation body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the applicant body or membership of any association or group, nor shall accreditation be conditional upon the number of bodies already accredited.

2.1.1.3 The accreditation criteria against which the competence of an applicant body is assessed shall be those outlined in the ISO/IEC Guides 40 and 62 or other normative documents relevant to the function performed. If an explanation is required as to the application of these documents to a specific accreditation programme, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the accreditation body.

2.1.1.4 The accreditation body shall confine its requirements, assessment and decisions on accreditation to those matters specifically related to the scope of the accreditation being considered.

2.1.2 Organization

The structure of the accreditation body shall be such as to give confidence in its accreditations.

In particular, the accreditation body shall

a) be impartial;

b) be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation;

c) identify the management (committee, group or person) which will have overall responsibility for all of the following:

1) performance of assessment and accreditation as defined in this Guide,

2) formulation of policy matters relating to the operation of the accreditation body,

3) decisions on accreditation,

4) supervision of the implementation of its policies,

5) supervision of the finances of the accreditation body,

6) delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;

d) have documents which demonstrate that it is a legal entity;

e) have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the accreditation body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system;

f) ensure that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;

g) have rights and responsibilities relevant to its accreditation activities;

h) have adequate arrangements to cover liabilities arising from its operations and/or activities;

i) have the financial stability and resources required for the operation of an accreditation system;

j) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing accreditation functions relating to the type, range and volume of work performed, under a responsible senior executive;

k) have a quality system, as outlined in 2.1.4, giving confidence in its ability to operate an accreditation system for certification/registration bodies;

l) have policies and procedures that distinguish between accreditation and any other activities in which the accreditation body is engaged;

m) together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;

n) have formal rules and structures for the appointment and operation of any committees which are involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions (see note 2);

o) ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditations and shall not offer or provide, directly or indirectly,

   1) those services that it accredits others to perform,

   2) consulting services to obtain or maintain accreditation,

   3) services to design, implement or maintain a certification scheme (see note 3);

p) have policies and procedures for the resolution of complaints, appeals and disputes received from bodies or other parties about the handling of accreditation or any related matters.

NOTES

2 A structure where members are chosen to provide a balance of interests, where no single interest predominates, will be deemed to satisfy this provision.

3 Other products, processes or services may be offered, directly or indirectly, provided they do not compromise confidentiality or the objectivity or impartiality of its accreditation process and decisions.

2.1.3 Subcontracting

When an accreditation body decides to subcontract work related to accreditation (e.g. audits) to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflict of interests, shall be drawn up. The accreditation body shall

a) take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending or withdrawing accreditation;

b) ensure that the subcontracted body or person is competent and complies with the applicable provisions of this Guide and is not involved, either directly or through its employer, with the design, implementation or maintenance of a certification or certification/registration scheme in such a way that impartiality could be compromised;

c) obtain the consent of the applicant or accredited body.

NOTE 4 Requirements a) and b) are also relevant, by extension, when an accreditation body uses, for granting its own accreditation, work provided by another accreditation body with which it has signed an agreement.

2.1.4 Quality system

2.1.4.1 The management of the accreditation body with executive responsibility for quality shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

2.1.4.2 The accreditation body shall operate a quality system in accordance with the relevant elements of this Guide and appropriate to the type, range and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the staff of the accreditation body. The accreditation body shall ensure effective implementation of the documented quality system procedures and instructions. The accreditation body shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to

a) ensure that a quality system is established, implemented and maintained in accordance with this Guide;

b) report on the performance of the quality system to the management of the accreditation body for review and as a basis for improvement of the quality system.

2.1.4.3 The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following:

a) a quality policy statement;

b) a brief description of the legal status of the accreditation body, including the names of its owners, if applicable, and, if different, the names of the persons who control it;

c) the names, qualifications, experience and terms of reference of the senior executive and other accreditation personnel influencing the quality of the accreditation function;

d) an organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those taking decisions regarding accreditation;

e) a description of the organization of the accreditation body, including details of the management (committee, group or person) identified in 2.1.2 c), its constitution, terms of reference and rules of procedure;

f) the policy and procedures for conducting management reviews;

g) administrative procedures including document control;

h) the operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;

i) the policy and procedures for the recruitment and training of accreditation body personnel (including auditors) and monitoring their performance;

j) a list of its subcontractors and details of the procedures for assessing, recording and monitoring their competence;

k) its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;

l) the policy and procedures for implementing the accreditation process, including

1) the conditions for issue, retention and withdrawal of accreditation documents,

2) checks of the use and application of documents used in the accreditation,

3) the procedures for assessing and accrediting applicants,

4) the procedures for surveillance and reassessment of accredited bodies;

m) the policy and procedures for dealing with appeals, complaints and disputes;

n) the procedures for conducting internal audits based on the provisions of ISO 10011-1.

2.1.5 Conditions for granting, maintaining, extending, reducing, suspending and withdrawing accreditation

2.1.5.1 The accreditation body shall specify the conditions for granting, maintaining, extending and reducing accreditation, and the conditions under which accreditation may be suspended or withdrawn, partially or in total, for all or part of the accredited body's scope of accreditation. In particular, the accreditation body shall require the body to notify it promptly of any intended changes to the quality system or other changes which may affect conformity.

2.1.5.2 The accreditation body shall have procedures to

a) grant, maintain, withdraw and suspend accreditation;

b) extend or reduce the scope of accreditation;

c) conduct reassessment in the event of changes significantly affecting the activity and operation of the accredited body (such as change of ownership, changes in personnel or equipment), or if analysis of a complaint or any other information indicates that the accredited body no longer complies with the requirements of the accreditation body.

2.1.6 Internal audits and management reviews

2.1.6.1 The accreditation body shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality system is being implemented and is effective. The accreditation body shall ensure that

a) personnel responsible for the area audited are informed of the outcome of the audit;

b) corrective action is taken in a timely and appropriate manner;

c) the results of the audit are documented.

2.1.6.2 The top management of the accreditation body shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this Guide and the stated quality policy and objectives. Records of such reviews shall be maintained.

2.1.7 Documentation

2.1.7.1 The accreditation body shall document, update at regular intervals, and make available (through publications, electronic media or other means), on request,

a) information about the authority under which the accreditation body operates;

b) a documented statement of its accreditation system, including its rules and procedures for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;

c) information about the assessment and accreditation process;

d) a description of the means by which the accreditation body obtains financial support, and general information on the fees charged to applicants and accredited bodies;